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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,802	EGGEN ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-46 and 48-54* is/are pending in the application.

4a) Of the above claim(s) *40,43 and 50-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-39,41,42,44-46,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/199,805.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see paragraph 15*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/28/2005*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of Applicants' response to a non-compliance letter, which was dated on July 7, 2005.

Status of the Claims

2. Claims 28-46 and 48-54 are currently pending.

3. Applicant's response to the Restriction and/or Election of Species requirements is acknowledged. Applicants elected ***with traverse*** Group I (i.e., claims 28-46 and 48-54) (see below i.e., ***Response to Restriction and/or Election of Species***).

4. Please note: Applicant's elected species (Subgroup 2 = sodium chloride and Subgroup 3 = ethyl acetate) were found in the art. Furthermore, Applicant's elected species (Subgroup = benzyl β-alaniate) was searched and was not found in the prior art. Thus, the search was expanded to non-elected species, which *were* found in the prior art, see rejections below. Also, see MPEP § 803.02 (emphasis added):

> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species.*** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action

made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Claims 40, 43 and 50-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species (e.g., see 7/7/05 Response, page 7, "Applicants specifically states that ... Claim 50 does not read on the elected species. Further, Applicant specifically states that previously presented Claims 51-54 do not read on the elected species; see also ***Response to Restriction and/or Election of Species*** below). Please note that claims 40 and 43 are also withdrawn from consideration because Applicants' elected benzyl β-alaninate does not represent a "polyamine" as required by the claim.

6. Therefore, claims 28-39, 41, 42, 44-46, 48 and 49 are examined on the merits in this action.

Response to Restriction and/or Election of Species

7. Applicant's election of Group I (i.e., claims 28-46 and 48-54) **with traverse** is acknowledged.

8. The traversal is on the ground(s) that "... Claim 47, the second Group, depends from Claim 28, the first independent Claim of Group I. Accordingly, it carries all of the limitations of Group 1, i.e., Group II caries all the limitations of Group I. Applicant fails to see how searching Group I and II is a burden" (e.g., see 10/25/04 Response, page 5, second to last paragraph). In addition, applicants argue, "... there is a definite relationship between the Claims ... Claim 47 simply further limits Claim 28 ... Therefore, as the two Groups are neither independent nor

distinct, the restriction is improper" (e.g., see 10/25/04 Response, paragraph bridging pages 5 and 5).

9. These arguments were fully considered but were not found persuasive. First, the Examiner contends that Applicants' arguments are moot in view of the cancellation of claim 47 (i.e., there are no claims drawn to Group II pending in the present application). Second, assuming, *arguendo*, that this issue was somehow still pending in the present case, the Examiner contends that Groups I and II are properly restricted for the reasons of record (e.g., see 6/16/04 Restriction, paragraphs 1-3 showing the Groups to be patentably distinct and also separately classified, thus establishing a *prima facie* search burden). In addition, to the extent that Applicants are arguing for a *per se* rule prohibiting restriction of patentably distinct subject matter as long as that patentably distinct subject matter is written in a "dependent" form, the Examiner contends that no such rule exists. According to MPEP § 803, there are two criteria for a proper restriction between patentably distinct inventions:

> (A) The inventions must be independent or distinct as claimed: and
> (B) There must be a serious burden on the Examiner if restriction is required.

Thus, it does not matter for purposes of restriction whether the claims are written in an "independent" or "dependent" form as long as the restriction requirements (A) and (B) set forth in MPEP § 803 are met. Here, both requirements are met because as stated in the Restriction Requirement dated 2/19/2004, these inventions (Groups I and II) have acquired a separate status in the art as shown by their different classification (e.g., see 2/19/04 Restriction, paragraph 1, wherein Group I is classified in class 530, whereas Group II is classified in class 435, subclass 6) and/or divergent subject matter (e.g., see reasons outlined in 2/19/04 Restriction, paragraph 3).

Thus, the different methods would require different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Thus, this does create an undue search burden for the Office.

10. Applicant's election of species is also acknowledged.

11. The election of species traversal is on the ground(s) that "... The Examiner has not properly ... stated why the species are patentably distinct ... [with regard to subgroup 2] the Examiner has not identified the species so it is impossible to make a determination ... [with regard to subgroup 3] Vague statements are no evidence of support ... [with regard to subgroup 4] Applicant finds it hard to imagine that a temperature range creates a species" (see 10/25/04 Response, pages 6 and 7).

12. These arguments were found to be persuasive in part. The subgroup 4 species election is herby withdrawn. All other species elections are maintained for the reasons of record (e.g., see 6/16/04 Restriction, paragraph 8). Furthermore, the Examiner notes that the species election is set forth with the same specificity as Applicants' claims. MPEP § 808.01(a) states, "In all applications in which no species claims are present and a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required, a requirement for an election of species should be made prior to a search of the generic claim." Here, Applicants scavenger is not limited in any way other than by the fact that it contains an amine and a latent anion. Thus, the amine scavenger reads on virtually an infinite number of

possibilities, which the Examiner submits would be burdensome to search. Likewise, no restrictions are placed on the structures of the extraction reagent and/or solvent, which again would read on an infinite number of structurally unrelated possibilities. Therefore, this does create an undue search burden.

13. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

14. The information disclosure statements filed 6/8/04, 1/20/04, 12/15/03, 10/23/03, fail, in part, to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because many of the publications cited therein lack inventor names and issue dates for the U.S. patents (e.g., see references cited in 6/8/04 and 1/20/04 IDS), title for non-patent literature (e.g., see references cited in 1/24/04 IDS), or dates (e.g., see 10/23/03 IDS, reference AR) which are necessary elements for consideration. While the other patent and other publications cited therein, and supplied, therewith, have been considered as to the merits, these three publications have not. Applicant is advised that the date of any re-submission of these citations contained in this information disclosure statement or the submission of the missing element – their publication dates – will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

15. The references listed on applicant's PTO-1449 form have been considered by the Examiner. A copy of the form is attached to this Office Action (e.g., 6/23/04, 6/8/04, 1/20/04, 11/15/03, 10/23/03).

Priority

16. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a nonprovisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Here, Applicants preliminary amendment does not include the relationship (e.g., see 10/23/03 Preliminary amendment, "This application is related to US patent application 10/199,804, filed July 19, 2002"). Thus, the amendment does not specify whether the current application is a "divisional" or not. In addition, no application data sheet was filed. Therefore, the effective filing date of the claims is the filing date of the case i.e., **October 23 2003**.

Specification

17. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an

application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a nonprovisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

18. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Objections to the Claims

19. Claim 48 is objected to because of the following informalities:

A. Claim 48 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The Examiner notes that Applicants' claims sets forth a method that is to be used for "automated" solution synthesis of peptides. However, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190

USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Objections to the Claims

20. Claim 28 is objected to because of the following informalities:

A. Claim 28 mistakenly contains the word "of" in the phrase "comprising of an activated carboxylic" in step (a). Correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 28, 30, 31, 36, 41, 42, 44-46, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpino et al. (Carpino, et al. "The 1,1-Doxobenzo[b]thiophene-2-ylmethyloxycarbonyl (Bsmoc) Amino-Protecting Group J. Org. Chem. 1999, 64, 4324-4338) (10/23/03 IDS Reference AR) as evidenced by Solomons (Solomons, T. W. G. Organic Chemistry Fifth Edition. New York: John Wiley and Sons. 1992, page 94, Table 3.1).

For ***claims 28 and 48***, Carpino et al. disclose processes for the rapid solid phase and/or solution phase peptide synthesis using Bsmoc amino protecting groups in conjunction with various scavenging agents (e.g., see abstract), which anticipates claim 28. For example, Carpino et al. disclose **(a)** a coupling step, using an excess of an

activated carboxylic acid component to acylate an amino component (e.g., see Carpino et al., page 4329, scheme 1 wherein H-AA_1-OR is coupled to an excess of Bsmoc-AA_2-OH to form Bsmoc-AA_2-AA_1-OR using HATU and DIEA, the excess Bsmoc-AA_2-OH is removed by the $NH_2(CH_2CH_2)_3N$; see also page 4327, middle paragraph, "A second byproduct, derived from excess acylating agent, is the amide 16"). Carpino et al. further disclose **(b)** a quenching step in which a scavenger is used to remove residual activated carboxylic acid and also using said scavenger to deprotect the growing peptide (e.g., see page 4329, scheme 1 wherein the Bsmoc protecting group and the excess AA_2 are removed; see also page 4327, compounds 15 and 16). Carpino et al. disclose **(c)** the use of one or more aqueous extractions (e.g., see page 4329, scheme 1 showing removal of water soluble side products; see also page 4327, middle paragraph; see also abstract, "Application [of Bsmoc amino-protecting groups] ... represents a significant improvement over the corresponding Fmoc-based method for rapid solution synthesis due to the opportunity to use water or saturated sodium chloride solution rather than an acidic phosphate buffer to remove [i.e., extract] all byproducts"). Carpino et al. also disclose at least one step (b), referred to as step (b'), in which an amine comprising a free anion or a latent anion is used as a scavenger of residual activated carboxylic acid (e.g., see page 4329, column 1, first paragraph wherein "ethanolamine" is disclosed). The reference does not state that ethanolamine possesses a "free anion or latent anion", but the Examiner contends that this would be an inherent property of ethanolamine via the following equilibrium in water $NH_2CH_2CH_2OH \rightleftharpoons NH_2CH_2CH_2O^- + H^+$) (e.g., see Solomons, page 94, Table 1, wherein pK_A of alcohol is ~16). "When the PTO shows a

sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.)." Finally, Carpino et al. also disclose repeating steps (a)-(c) above to synthesize a full-length peptide and/or protein (e.g., see page 4329, wherein "additional cycles" are disclosed; see also experimental section wherein longer peptides are produced). With regard to claim 48, the limitation "automated solution synthesis" in the preamble has not been afforded any patentable weight. The Examiner notes that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

For ***claim 30***, Carpino et al. disclose pre-activation of carboxylic acid, for example, via cyanuric fluoride to produce acid fluorides (e.g., see paragraph bridging pages 4332-4333 showing activation via cyanuric fluoride; see also scheme 1 wherein HATU + DIEA is disclosed).

For ***claim 31 and 36***, Carpino et al. disclose ethanolamine, which is used as a scavenger (e.g., see page 4329, column 1, paragraph 1; see also Solomons, page 94, Table 1 showing anion).

For ***claim 41***, Carpino et al. disclose one or more cycles wherein in step (b) both quenching and deptrotection occur and the subsequent step (c) comprises sequential neutral extractions (e.g., see page 4320, Scheme 1, Bsmoc-AA_2-AA_1-OR → H-AA_2-AA_1-OR step; see also experimental; see also page 4327, column 2, middle paragraph, "It has now been found that the process can be simplified by switching to Bsmoc chemistry since the byproduct adduct 15 formed in this case is soluble in water, thus avoiding the need for extraction with an acidic buffer. This results in fewer complications with emulsions and loss of growing peptide into the aqueous phase.).

For ***claim 42***, Carpino et al. disclose the use of sodium chloride (e.g., see abstract, "Application to the latter methodology represents a significant improvement over the corresponding Fmoc-based method for rapid solution synthesis due to the opportunity to use water or saturated sodium chloride solution rather than an acidic phosphate buffer to remove all byproducts").

For ***claim 44***, Carpino et al. disclose the use of ethyl acetate (e.g., see generally experimental section; see also page 4332, Methods 2 and 3 see also Table I, Bsmoc-Leu-OH entry). In addition, the Examiner notes, "the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA1955). Here, the choice of solvent would be routine.

For ***claims 45 and 46***, Carpino et al. disclose, for example, room temperature, which falls within 0 to 50°C (e.g., see Experimental).

For ***claim 49***, Carpino et al. disclose, for example, the use of TFA to acidolytically remove the permanent protecting groups (e.g., see Scheme 1, last step).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 28-31, 36, 41, 42, 44-46, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino et al. (Carpino, et al. "The 1,1-Doxobenzo[b]thiophene-2-ylmethyloxycarbonyl (Bsmoc) Amino-Protecting Group J. Org. Chem. 1999, 64, 4324-4338) (10/23/03 IDS Reference AR) and Tolle et al. (WO 00/71569) (Published November 30, 2000)

and Houghten et al. (Houghten, R.A.; Pinilla, C.; Blondelle, S.E.; Appel, J.R.; Dooley, C.T.; Cuervo, J.H. "Generation and use of synthetic peptide combinatorial libraries for basic research and drug discovery" *Nature* 1991, *354*, 84-86).

For ***claims 28, 30, 31, 36, 41, 42, 44-46, 48 and 49***, Carpino et al. teach all the limitations stated in the 35 U.S.C. 102(b) rejection above (incorporated in its entirety herein by reference), which anticipates and, as a result, renders obvious claims 28, 30, 31, 36, 41, 42, 44-46, 48 and 49.

The prior art teaching of Carpino et al. differ from the claimed invention as follows:

For ***claim 29***, the prior art teachings of Carpino et al. differ from the claimed invention by not specifically reciting the amounts of reagents as carboxylic component, coupling additive greater than coupling reagent greater than amino component. Carpino et al. only show caboxylic component greater than amino component.

However, the combined references of Tolle et al. and Houghten et al. teach the following limitations that are deficient in Carpino et al.:

For ***claim 29***, the combined teachings of Tolle et al. and Houghten et al. teach the use of coupling reagents used in conjunction with coupling additives (e.g., see Tolle et al., page 11, line 3 wherein activated N-hydroxysuccinimide esters are used; see also Houghten et al., Tables and figure). In addition, differences in concentration (e.g., carboxylic component, coupling additive greater than coupling reagent greater than amino component) will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here

the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235Carpino(CCPA 1955). Here, it would be conventional and within the skill of the art to *identify the optimal concentration*. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F. 2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

For ***claim 48***, the combined teachings of Tolle et al. and Houghten et al. also disclose the use of automation (e.g., see Tolle et al. figure 2) in the alterative that Applicants' preamble were to be afforded patentable weight, which it is not (see above).

It would have been obvious to one skilled in the art at the time the invention was made to use the scavenging resins for the combinatorial synthesis of proteins as taught by the combined teachings of Tolle et al. and Houghten et al. with the Bsmoc Amino protecting groups as taught by Carpino et al. because Carpino et al. state that their method can be used with scavenging resins and that it is also applied to combinatorial synthesis i.e., the references represent analogous art. Furthermore, one of ordinary skill in the art would have been motivated to use the scavenging resins as taught by Tolle et al. because Tolle et al. explicitly state that their resins will "minimize the requirement for isolation of intermediates" that are produced in peptide synthesis using scavengers (see Carpino et al., Field of the invention), which would encompass the peptide synthesis disclosed by Carpino et al. In addition, Houghten et al. teach that their "split and mix" method can be advantageously used to produce large peptide libraries (e.g., see Houghten

et al., abstract), which would encompass the peptide libraries of Carpino et al. Finally, one of ordinary skill in the art would have reasonably expected to be successful because all three references teach the successful synthesis of peptides and both Carpino et al. and Tolle et al. teach successful examples of using amine scavengers in peptide synthesis.

Double Patenting

Claim Rejections – 35 USC § 101

24. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 USC 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

25. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

26. Claims 28-39, 42, 44-46, 48 and 49 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 28-39, 42, 46-48, 50 and 51 of copending Application No. 10/692,354 (2004/0082760 A1) (referred to herein as '354). This is a

provisional double patenting rejection since the conflicting claims have not in fact been patented. The examiner notes that the '354 application recites a "rapid" solution synthesis in the preamble, which was not recited in the present application, but this limitation has not been afforded any patentable weight. Thus, the claimed scope is identical. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

28. Claims 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41 of copending Application No. 10/692,354 (2004/0082760 A1) (referred to herein as '354). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined

application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986). Although the conflicting claims are not identical, they are not patentably distinct from each other because, for example, claim 41 is generic to all that is recited in claim 41 of '354 and/or represents overlapping scope. Here, the "basic" extractions disclosed in claim 41 of '354 anticipate claim 41 of the present invention. Furthermore, it would have been obvious to one having ordinary skill in the art to modify embodiments of '354 that fall outside the scope of the present application (e.g., the acidic extractions) to select a specifically disclosed embodiment that falls within the scope of the present application (e.g., the basic or neutral extractions) because these embodiments describe similar method steps (e.g., extraction) with similar results (e.g., purification). One having ordinary skill in the art would have been motivated to do this because these embodiments (e.g., neutral and basic extractions) are disclosed as being preferred embodiments in the '354 application and the dependent claims of '354 teach toward Applicants' claimed invention (e.g., see claims 42 and 43 of the '354 application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

29. Claims 28-39, 41, 42, 44-46, 48 and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,864,357 (referred to herein as '357). An obviousness-type double patenting rejection is

appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986). Although the conflicting claims are not identical, they are not patentably distinct from each other because, for example, claims 28-39, 41, 42, 44-46, 48 and 49 are generic to all that is recited in claims 1-14 of '357. That is, claims 1-14 of '357 fall entirely within the scope of claim 28-39, 41, 42, 44-46, 48 and 49 of the present application or, in other words, claims 28-39, 41, 42, 44-46, 48 and 49 of the present application are anticipated by claims 1-14 of '357. Specifically, **[1]** both applications recite a coupling step wherein an excess of a molecule comprising an activated carboxylic acid us used to acylate an amino component (e.g., compare claim 28, step (a) of the present application to claim 1, lines 2-3 of '357), **[2]** both applications recite a quenching step in which a scavenger is used to remove residual activated carboxylic functions and wherein the scavenger is an amine that contains a free or latent anion (e.g., compare claim 28, step (b) of the present application to claim 12 of '357 wherein benzyl β-alaniate is disclosed, which anticipates step (b)) and **[3]** both application disclose one or more extractions (e.g., compare claim 28, step (c) of the present application to last two lines of claim 1 in '357). In addition, both references disclose temporary protecting groups (e.g., compare claim 2 of '357 to claim 32 of the present application), peptide synthesis (e.g., compare claim 3 of '357 to preamble of claim 28 of the present application), permanent protecting groups (e.g., compare 4 of '357 to claim 49 of the present application), protecting groups that are hydrogenolyticaly removable with the same

lability (e.g., compare claims 5 and 6 of '357 to claims 33 and 34 of the present application), permanent protecting groups that are acidolytically removable (e.g., compare claim 7 of '357 to claim 49 of the present application), a benzyl β-alaniate scavenger (e.g., compare claims 9-12 of '357 to claim 39 of the present application), "solution" phase synthesis (e.g., compare claim 13 of '357 to claim 28 of the present application) and aqueous extractions (e.g., compare claim 14 of '357 to claim 28, step(c) of the present application).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 30, 2005